REMARKS

Reconsideration of the Final Office Action mailed February 17, 2004, (hereinafter "instant Office Action") and withdrawal of the rejection of claims 1-3 are respectfully requested.

In the instant Office Action, claims 1-3 are listed as pending and claims 1-3 are listed as rejected.

The Examiner has rejected claims 1-3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,403,641 (Heal et al.), alleging that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to the treatment of co-morbid conditions associated with obesity, while the patented claims are directed to the treatment of obesity, *per se*, in which the same combination of active agents are employed". Applicants respectfully traverse this rejection.

Applicants submit that claims 1-3 of the instant application are not obvious in view of U.S. Patent No. 6,403,641. U.S. Patent No. 6,403,641 are directed to treatment of obesity, whereas the instant application is directed to treatment of co-morbid conditions associated with obesity. As argued in Applicants' Reply filed June 17, 2004, co-morbid conditions are separate and distinct from obesity. Applicants list, on page 3, lines 6-13, several examples of co-morbid conditions, each of which is recognized as a distinct disorder. None of these conditions would traditionally be treated with a combination of anti-obesity drugs. The first line, standard therapy is to treat the co-morbid condition(s) separately from the obesity using a different therapeutic from that used to treat the obesity. Applicants have discovered that administering the combination of orlistat and sibutramine to an obese patient treats the co-morbid conditions associated with obesity. This is a departure from the typical pharmacological approach taken by health care professionals. Thus, it is not obvious that one would use the combination of orlistat and sibutramine to treat co-morbid conditions associated with obesity.

In order for an invention to be considered obvious under 35 U.S.C. 103(a), the invention must be considered as a whole, there must be some motivation or suggestion in the prior art reference itself to modify the reference, and there must be a reasonable expectation of success. The Examiner has not established a *prima facie* case of obviousness. In order to have a *prima*

facie case of obviousness, there must be a specific suggestion or motivation to modify the reference, there must be an expectation of success and the prior art reference must teach or suggest all of the claim limitations.

The Examiner has not pointed to any suggestion or motivation for one skilled in the art to modify U.S. Patent No. 6,403,641. Nor has the Examiner presented any line of argument as to why one skilled in the art would be motivated to use the combination of sibutramine and orlistat to treat co-morbid conditions associated with obesity. In fact, there is no motivation or suggestion to modify U.S. Patent No. 6,403,641 for treatment of co-morbid conditions associated with obesity.

Without such an express suggestion or an explanation as to why the Examiner alleges the claims to be obvious, the standard for a *prima facie* case of obviousness is not met. U.S. Patent No. 6,403,641 does not disclose, teach or suggest the use the combination of sibutramine and orlistat to treat co-morbid conditions associated with obesity. There is no motivation in U.S. Patent No. 6,403,641 to use the combination of sibutramine and orlistat to treat co-morbid conditions associated with obesity.

When the prior art fails to suggest the claimed invention as a whole, as it does here, any reconstruction of the prior art to obtain that invention necessarily and inevitably requires impermissible hindsight.

MPEP §2143

It is well recognized that:

> Hindsight reconstruction of a claimed invention, absent a teaching or suggestion in the art is impermissible.

As explained by the CAFC in W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F. 2d 1540, 1553 (Fed. Cir. 1983), 220 USPQ 303, 312-13, cert. denied 53 U.S.L. Week 3239 (October 1, 1983):

> To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

> It is difficult but necessary that the decision-maker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.

Other citations:

"When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself". ACS Hospital Systems, Inc. v. Montefoire Hospital, 732 F. 2d 1572, 1577 & n. 14, 221 USPQ 929, 933 & n. 14 (Fed. Cir. 1984). "There must be 'something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination". Lindemann Maschinefabric GmbH v. American Hoist and Derrick Co., 730 F. 2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984), Interconnect Planning Corp. v. Feil, 774 F. 2d1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).

Applicants submit that the Examiner forms his arguments based upon the teachings of the instant application rather than what is actually motivated by the prior art. This is a telltale sign that the Examiner has used hindsight to formulate the obviousness rejection. Another sign is that the cited prior art reference does not result in any of the inventions of claims 1-3.

Therefore, the rejection of Claims 1-3 under the judicially created doctrine of obviousness-type double patenting over claims 1-3 of U.S. Patent No. 6,403,641 is obviated and should be withdrawn.

No fees are due for the instant amendment since the total number of claims after entry of the amendments hereinabove is not more than the total number of claims that Applicants have paid for to date.

Based upon the foregoing, Applicants believe that claims 1-3 are in condition for allowance. Prompt and favorable action is earnestly solicited.

If the Examiner believes that a telephone conference would advance the condition of the instant application for allowance, Applicants invite the Examiner to call Applicants' agent at the number noted below.

Respectfully submitted,

Date: July 19, 2004

Gayle O'Brien
Agent for Applicants
Reg. No. 48,812

Abbott Bioresearch Center
100 Research Drive
Worcester, MA 01605
(508) 688-8053